PTO/SB/21 (09-04)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	07/579,269
Filing Date	September 5, 1990
First Named Inventor	Dennis L. Panicali
Art Unit	1648
Examiner Name	Laurie A. Scheiner
Attorney Docket Number	20953-040736

ENCLOSURES *(Check all that apply)*

- [X] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [X] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [X] Other Enclosure(s) (please Identify below):

See 1 in Addendum

Remarks

The Commissioner is authorized to charge the NIXON PEABODY LLP Deposit Account No. 50-0850 for fees associated with this submission.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	NIXON PEABODY LLP, 100 Summer Street, Boston, MA 02110-2131		
Signature			
Printed name	David S. Resnick		
Date	4/11/05	Reg. No.	34,235

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Nicole M. Aguirre	Date	4/11/05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Dennis L. Panicali et al.		
Application No.:	07/579,269	Group No.:	1648
Filed:	09/05/1990	Examiner:	Laurie A. Scheiner
Title:	RECOMBINANT POX VIRUS FOR IMMUNIZATION AGAINST TUMOR-ASSOCIATED ANTIGENS		

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. § 1.8(a) and 1.10)

I hereby certify that this correspondence:

1. Transmittal Form in duplicate (4 pp.);
2. Petition to Reset Period For Response Due to Postmark Date Being Later Than Mail Date Printed on PTO Action in duplicate (4 pp.);
3. Evidence and Statement Accompanying Petition to Reset Period for Response Due to Postmark Being Later Than Mail Date Printed on PTO Action in duplicate (4 pp.);
4. Copy of the Supplemental Examiner's Answer date stamped "Received February 4, 2005 NIXON PEABODY LLP" in duplicate (10 pp.);
5. Copy of the U.S. Post Office "Return to Sender" bar coded label dated January 21, 2004 and the original post marked envelope indicative of the Post Office return stamped received by TECH CENTER 1600/2900 on January 29, 2004 in duplicate (2 pp.);
6. Copy of the Bib Data Sheet on file in the US PTO in duplicate (2 pp.);
7. Fee Transmittal in duplicate (2 pp.);
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Date: April 11, 2005

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(*type or print name of person certifying*)

PTO/SB/17 (12-04v2)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($)	130.00

Complete if Known	
Application Number	07/579,269
Filing Date	September 5, 1990
First Named Inventor	Dennis L. Panicali
Examiner Name	Laurie A. Scheiner
Art Unit	1648
Attorney Docket No.	10953-040736

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 50-0850 Deposit Account Name: NIXON PEABODY LLP

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WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 20 or HP =	_____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 3 or HP =	_____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims Fee ($)	Multiple Dependent Claims Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____	/ 50 = _____ (round up to a whole number) x	125.00	= 0.00

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): Petition to Reset Period for Response	130.00

SUBMITTED BY

Signature	[signature]	Registration No. (Attorney/Agent) 34,235	Telephone 617-345-6057
Name (Print/Type)	David S. Resnick		Date 4/11/05

IFW

Atty. Docket No. 700953-040736 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Dennis L. Panicali et al.		
Application No.:	07/579,269	Group No.:	1648
Filed:	09/05/1990	Examiner:	Laurie A. Scheiner
Title:	RECOMBINANT POX VIRUS FOR IMMUNIZATION AGAINST TUMOR-ASSOCIATED ANTIGENS		

CERTIFICATE OF MAILING (37 C.F.R. SECTION 1.8(a))

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the united States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to MAIL STOP PETITIONS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

4/11/05
Date

Nicole M. Aguirre
(*type or print name of person mailing paper*)

Nicole M. Aguirre
(*signature of person mailing paper*)

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO RESET PERIOD FOR RESPONSE DUE TO POSTMARK DATE BEING LATER THAN MAIL DATE PRINTED ON PTO ACTION

Applicants respectfully request that the Supplemental Examiner's Answer mailed January 13, 2004, be re-mailed to the undersigned, thus resetting the reply.

1. This petition is being filed to restart the period of response to the PTO action indicated to have been mailed on January 13, 2004.

2. The response period was set for 2 months from the initial mailing date of the Supplemental Examiner's Answer – March 13, 2004.

04/14/2005 AWONDAF1 00000015 500850 07579269
01 FC:1464 130.00 DA

3. Enclosed herewith is:

(a) evidence showing the date of receipt of the PTO action at the correspondence address;

(b) a copy of the envelope that contained the PTO action showing the mailed correspondence returned to the PTO by the Post Office due to an incorrect address – as well as the correct address of record at the time of mailing as indicated in the PTO "Bib Data Sheet".

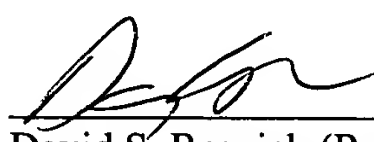
It is respectfully requested that the Supplemental Examiner's Answer be re-mailed to the following current address associated with customer 50187:

Ronald I. Eisenstein
Nixon Peabody, LLP
100 Summer Street
Boston, Massachusetts 02110.

The Commissioner is authorized to charge any fees associated with this petition to the NIXON PEABODY LLP Deposit Account No. 50-0850. A duplicate copy of this paper is submitted herewith.

Date: 4/11/05

Respectfully submitted,



David S. Resnick (Reg. No. 34,235)
NIXON PEABODY LLP
100 Summer Street
Boston, MA 02110
(617) 345-6057

Attachment to (PTO/SB/21) Transmittal Form (continued)

1. Evidence & Statement Accompanying Petition to Reset Period for Response Due to Postmark Date Being Later Than Mail Date Printed on PTO Action; Copy - Supplemental Examiner's Answer; Copy - U.S. Post Office "Return to Sender" bar codecoded label and original post marked envelope indicative of return to sender; Copy - Bib Data Sheet; Certificate of Mailing; and Return Receipt Postcard.

Atty. Docket No. 700953-040736 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Dennis L. Panicali et al.		
Application No.:	07/579,269	Group No.:	1648
Filed:	09/05/1990	Examiner:	Laurie A. Scheiner
Title:	RECOMBINANT POX VIRUS FOR IMMUNIZATION AGAINST TUMOR-ASSOCIATED ANTIGENS		

CERTIFICATE OF MAILING (37 C.F.R. SECTION 1.8(a))

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4/11/05
Date

Nicole M. Aguirre
(type or print name of person mailing paper)

Nicole M. Aguirre
(signature of person mailing paper)

MAIL STOP PETITIONS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

EVIDENCE AND STATEMENT ACCOMPANYING PETITION TO RESET PERIOD FOR RESPONSE DUE TO POSTMARK DATE BEING LATER THAN MAIL DATE PRINTED ON PTO ACTION

1. I, David S. Resnick, hereby state that the Action mailed by the PTO on January 13, 2004, as shown on the first page thereof which accompanies this petition, was received on February 4, 2005.

2. The evidence showing the date of receipt of the PTO action at the correspondence address of the applicant is as follows:

   (a) Copy of the Supplemental Examiner's Answer date stamped "Received February 4, 2005 NIXON PEABODY LLP".

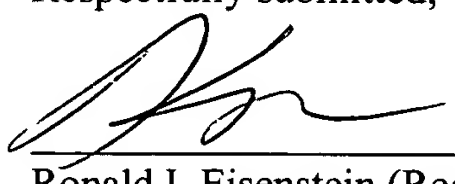
(b) Copy of the U.S. Post Office "Return to Sender" bar coded label dated January 21, 2004 and the original post marked envelope indicative of the Post Office return stamped received by TECH CENTER 1600/2900 on January 29, 2004;

(c) Copy of the Bib Data Sheet on file in the US PTO indicative of the correct address at the time of mailing.

I can state that the above evidence establishes the date of the postmark and the date of receipt of the Office Action because Applicants note that the Supplemental Examiner's Answer was mailed to Ronald I. Eisenstein at his previous firm, Dike, Bronstein, Roberts & Cushman. The Response was then returned to the U.S. Patent and Trademark Office and was not re-mailed until on or about February 2005. Applicants note that the Patent and Trademark Office had Mr. Eisenstein's correct mailing address as noted in the Bib Data Sheet attached to the Supplemental Examiner's Answer, a copy of which is enclosed herewith.

Date: 4/11/05

Respectfully submitted,



Ronald I. Eisenstein (Reg. No. 30,628)
David S. Resnick (Reg. No. 34,235)
NIXON PEABODY LLP
100 Summer Street
Boston, MA 02110
(617) 345-6057

UNITED STATES PATENT AND TRADEMARK OFFICE

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1643

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/579,269	09/05/1990	DENNIS O'DANIELE	ABT87-01	4396

EXAMINER	
SCHEINER, LAURIE A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/13/2004

7590 01/13/2004

RONALD I. EISENSTEIN
DIKE, BRONSTEIN, ROBERTS & CUSHMAN
130 WATER STREET
BOSTON, MA 02109

Please find below and/or attached an Office communication concerning this application or proceeding.

40736

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 34

Application Number: 07/579,269
Filing Date: September 05, 1990
Appellants: PANICALI ET AL.

Ronald I. Eisenstein
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the Remand to the Examiner by the Board mailed August 7, 1998. In the remand, the Board expressed an intention to affirm the Office's rejections under one or more grounds as argued in the Examiner's Answer. However, the Board requested that the Office further consider the 35 U.S.C. § 112, first paragraph rejection in light of a prior art reference cited in the Final Rejection: the Lathe et al. reference. The Board has also requested that the Examiner reconsider the grounds of rejection in light of several previously unconsidered prior art references cited by the Board: the four Paoletti

et al. patents (Paoletti '112, '848, '330, '587), five references cited by Lathe, and the Schlom et al. abstract (Schlom). Upon consideration, the Office concludes, for the reasons set forth below, that the new references do not affect the analysis or rejections of the claims.

The Examiner has considered the four Paoletti patents and has determined that they are less relevant than, and do not add anything to the analysis of the claims over Lathe. The Examiner has also considered the five references cited by Lathe (Lathe references), and has found that they also add little to the determination of patentability of the application and claims at issue. The Lathe references provide little more than background in the art of the invention.

The Schlom reference is not quite so easily dismissed. At first glance, it appears relevant to the rejection based on §101 and §112 paragraph 1 of the United States Code. This reference will be addressed in more detail in the body of this Supplemental Answer, but upon consideration, the Office finds that the Schlom reference does not repair the deficiencies in the application's disclosure such that the claims may be allowed.

However, in light of the Applicants' failure to establish the utility and provide an enabling disclosure of the claimed invention, the Examiner feels that there is no current need to address the 35 U.S.C. § 103 rejections. Therefore, the §103 rejection to claims 15-22 as obvious over Lathe in view of Padhy et al., and further in view of Yamamoto et al. are hereby withdrawn.

1. Status of the Claims

The statement of the status of the claims contained in the Brief is correct. This appeal involves claims 15, 16, 18-22, 36, and 37.

2. Summary of the Invention

The summary of the invention contained in the Brief is correct.

3. Issues

The statement of the issues in the Brief is correct. This Supplemental Answer is intended as an addendum to the previous Examiner's Answer.

4. Grouping of the Claims

The Appellant's Brief states that the claims do not stand of fall together, but fails to provide any support for that statement as required under 37 C.F.R. 1.192(c)(7). The Appellant's statement that all claims are separately patentable is also unsupported.

5. Prior Art of Record

The following are lists of all priori art of record relied on by the Examiner in the Answer, as well as of those references considered by the Examiner for the purpose of responding to the Board's remand.

Prior Art Relied on by Examiner in the Answer

Allen et al., "Specificity of the T-cell Receptor: Two different Determinants are Generated by the Same Peptide and the I-A^k Molecule[1,2]," The Journal of Immunology, vol. 135, pp. 368-73 (1985).

Lathe et al. (Lathe), "Tumor Prevention and Rejection with Recombinant Vaccinia," Nature, vol. 326, pp. 878-80 (1987).

Padhy et al., " Identification of a Phosphoprotein Specifically Induced by the Transforming DNA of RAT Neuroblastomas," Cell, vol. 28, pp. 865-71 (1982).

Yamamoto et al., "Similarity of Protein Encoded by the Human c-erb-B-2 Gene to Epidermal Growth Factor Receptor," Nature, vol. 319, pp. 230-34 (1984).

Additional Prior Art Considered as per the Board's Request

Paoletti et al. (Paoletti '112), 4,603,112, July 29, 1986.

Paoletti et al. (Paoletti '848), 4,722,848, Feb. 2, 1988.

Paoletti et al. (Paoletti '330), 4,769,330, Sept. 6, 1988.

Paoletti et al. (Paoletti '587), 5,110,587, May 5, 1992.

The Lathe References

Drebin et al., "Monoclonal Antibodies Identify a Cell-Surface Antigen Associated with an Activated cellular Oncogene," Nature, vol. 312, pp. 545-48 (1984).

Koprowski et al., "Specific Antigen in Serum of Patients with colon Carcinoma," Science, vol. 212, pp. 53-56 (1981).

Peto, R. & H. Zur Hausen (Eds.), Banbury Report 21, Viral Etiology of Cervical Cancer, Cold Spring Harbor Laboratory, New York (1986).

Real, F.X. et al., "Class 1 (Unique) Tumor Antigens of Human Melanoma," Journal of Experimental Medicine, vol. 160, pp. 1219-33 (1984).

Ueda, R. et al., "Cell Surface Antigens of Human Renal Cancer Defined by Autologous Typing," Journal of Experimental Medicine, vol. 150, pp. 564-72 (1979).

6. Grounds of Rejection

This Supplemental Answer continues the analysis of the rejections based on 35 U.S.C. §101 and §112 paragraph 1.

7. Supplementary Response to the Argument

The claimed invention is a method of immunizing humans against human cellular oncogene encoded products by inoculating them with either a pox or vaccinia virus expressing the oncogene, proto-oncogene, or homologue thereto (all 3 inclusively

referred to as "oncogene"). The Appellants' claims have been rejected under 35 U.S.C. §101 for failure to establish the invention's utility, and under §112 paragraph 1 for failure to provide an enabling disclosure of the invention. Section 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

All of the claims at issue in this appeal are rejected under this section for failure to establish utility. As was argued in the Answer, this failure arises because the appellant's disclosure does not show that inoculating an individual with a virus expressing an oncogene (by expressing the oncogene product) would immunize that individual from tumors expressing such products.

In the Answer, the Examiner argued that the specification failed to show that such an inoculation would immunize an individual against tumors expressing oncogene products. The specification showed that while such an inoculation into mice seemed to cause them to reject tumors expressing the oncogene products, use of the same inoculation into rates failed to promote tumor rejection in rats. This showed that the mice could have been reacting because the oncogene was a foreign substance rather than because an immune response had been elicited. The failure of the rats to reject rat tumors expressing rat oncogene products created doubt that the claimed method would work in any situation where the subject was inoculated with a virus expressing a syngenic oncogene. This, in turn, created a question as to whether the claimed method would cause a human to reject tumors expressing human oncogene products. Thus, utility has not been shown.

Likewise, because the disclosure demonstrated that syngenic test subjects did not respond to the inoculation as the applicant claimed they should, the claims have not been enabled. Section 112 paragraph 1 of 35 U.S.C. reads as follows:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor for carrying out the invention."

The invention has not been enabled because the appellant did not show that the disclosed method of immunization would in fact immunize a human against a human oncogene product. Because the claimed method did not elicit an immune response in rate against rat oncogenes, the appellant has not shown that a human could be immunized against human oncogenes using the disclosed method. Since the method has not been shown to work, it is not enabled as required by §112 paragraph 1.

Effect of the Schlom Reference

The Schlom reference is an abstract of an article explaining the results of clinical trials of the disclosed method. The abstract states that the inoculation of a vaccinia virus expressing the human carcinoembryonic antigen (CEA) into cancer patients did yield an improved immune (CTL) response in those patients against cancer expressing CEA. However, while this may be encouraging, it is not sufficient to overcome the current rejections to the claims.

The claims on appeals all cover a virus expressing an oncogene, proto-oncogene, or an oncogene or proto-oncogene homologue product. See the Appendix to the Appeal Brief. Such genes have the potential to cause transformation of normal cells into tumor

cells if mutated from their wild-type form. Application, pp. 1, 3-4. Oncogenes may encode for proteins that operate inside the cell, or for cell surface proteins with internal effects (e.g. growth factor molecules). Application, pp. 3-4. The Applicant used an oncogene product in the viral antigen disclosed in the application pp. 24-36. It was this disclosed, oncogene product antigen that failed to work, thus giving rise to the rejections both for lack of utility and enablement.

Along with the oncogenes, Appellant's disclosure also mentioned another type of gene product that may be used in the immunization method disclosed. Application, p. 8. These tumor-associated molecules are not expressions of oncogenes, or even necessarily involved in cell transformation. Nevertheless, these molecules are still associated with tumors because they are expressed by tumor cells. Application, p. 8. The Appellants list CEA, the molecule tested in the clinical trials, as such a tumor-associated molecule, not as an oncogene product, pp.8.

Tumor-associated molecules are not expressions of oncogenes, and therefore do not fall within the invention claimed by the appellant. Genes encoding these molecules do not have the potential to transform cells, even where they may be involved in transformation, as do the oncogene antigens. The tumor-associated molecules are distinct from those molecules consisting if oncogene products. Similarly, the inoculation in the Schlom reference is distinct from the claimed invention. The effectivity of viral antigens using tumor-associated molecules does not establish to the patentability of the claimed method, which uses oncogene products as the antigen.

Nor can the successful use of such distinct molecules in a disclosed, but unclaimed, mode of use overcome a rejection based on an unsuccessful test of the

claimed method. Here, the claims are rejected because the Application failed to show the utility of, and to enable, the claimed mode of practicing the invention; i.e. using a viral antigen expressing an oncogene product. The Schlom reference does not relate to the claimed method. It shows only that a related, and disclosed, method may work. It is not sufficient to overcome the earlier evidence in the Application suggesting the inoperability of the claimed method itself. Thus, the Schlom reference does not establish utility of the invention, nor does it enable the disclosure. The reference is therefore not relevant in the present case.

Further Consideration of Lathe

Lathe discloses the use of recombinant vaccinia to elicit tumor immunity responses for tumors caused by the tumorigenic properties of the Polyoma virus. The authors of that reference took three tumor-specific antigens, three different early Polyoma proteins, and inserted each of the three into a different vaccinia recombinant. They found that two of the three recombinant vaccines lead to a regression of and, under certain circumstances, to an elimination of Polyoma transformed tumor cells injected into test animals. Their experiments showed that they could get such results in rats vaccinated both before and after inoculation with the tumor cells. While this reference does show potential promise for the future use of recombinant viral antigens in eliciting immune responses to tumors, it does not fill in the gaps of the Appellants' disclosure such that either the utility or enablement requirements are satisfied.

Lathe does not deal with syngenic oncogenes, as does the Appellants' invention, but with tumor-associated viral proteins. One of the elements of the Appellants' claimed invention is that the immune response be against a syngenic oncogene's product. The

Appellants' claims were rejected because they did not get such an immune response in response to inoculation with a viral antigen expressing that oncogene. Recognition of a foreign protein in an immune response is not a satisfactory substitute for recognition of a syngenic protein. Thus, Lathe is not relevant to the consideration of the claims under 35 U.S.C. § 101 and § 112 paragraph 1.

For the reasons stated above, it is believed that the rejections should be sustained.

This Application has been forwarded to the Board of patent Appeals and interferences for decision on the Appeal.

Respectfully submitted

James C. Housel
Supervisory Patent Examiner
Technology Center 1600

571-272-0902

Ronald I. Eisenstein
Dike, Bronstein, Roberts, & Cushman
130 Water Street
Boston, MA 02109

Organization TC 1600 CMI Bldg./Room

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BIBDATASHEET

Bib Data Sheet

CONFIRMATION NO. 4396

SERIAL NUMBER	FILING OR 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/579,269	09/05/1990 RULE	424	1648	ABT87-01

APPLICANTS

DENNIS L. PANICALI, ACTON; MA;
RENE BERNARDS, BROOKLINE, MA;

**** CONTINUING DATA **********

This application is a CON of 07/092,036 09/02/1987 ABN

**** FOREIGN APPLICATIONS **********

IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** SMALL ENTITY **
** 09/27/1990

		STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
Foreign Priority claimed ☐ yes ☐ no 35 USC 119 (a-d) conditions met ☐ yes ☐ no ☐ Met after Allowance Verified and Acknowledged Examiner's Signature Initials		MA	3	32	9

ADDRESS

RONALD I. EISENSTEIN
PEABODY & BROWN
101 FEDERAL STREET
BOSTON ,MA 02110

TITLE

RECOMBINANT POX VIRUS FOR IMMUNIZATION AGAINST TUMOR-ASSOCIATED ANTIGENS

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	

Application Number	07/579,269
Filing Date	September 5, 1990
First Named Inventor	Dennis L. Panicali
Art Unit	1648
Examiner Name	Laurie A. Scheiner
Attorney Docket Number	20953-040736

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ENCLOSURES *(Check all that apply)*

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- [ ] Fee Attached
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- [X] Other Enclosure(s) (please Identify below):

See 1 in Addendum

Remarks

The Commissioner is authorized to charge the NIXON PEABODY LLP Deposit Account No. 50-0850 for fees associated with this submission.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	NIXON PEABODY LLP, 100 Summer Street, Boston, MA 02110-2131		
Signature			
Printed name	David S. Resnick		
Date	4/11/05	Reg. No.	34,235

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Typed or printed name	Nicole M. Aguirre	Date	4/11/05

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Attachment to (PTO/SB/21) Transmittal Form (continued)

1. Evidence & Statement Accompanying Petition to Reset Period for Response Due to Postmark Date Being Later Than Mail Date Printed on PTO Action; Copy - Supplemental Examiner's Answer; Copy - U.S. Post Office "Return to Sender" bar codecoded label and original post marked envelope indicative of return to sender; Copy - Bib Data Sheet; Certificate of Mailing; and Return Receipt Postcard.

Atty. Docket No. 700953-040736

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Dennis L. Panicali et al.		
Application No.:	07/579,269	Group No.:	1648
Filed:	09/05/1990	Examiner:	Laurie A. Scheiner
Title:	RECOMBINANT POX VIRUS FOR IMMUNIZATION AGAINST TUMOR-ASSOCIATED ANTIGENS		

CERTIFICATE OF MAILING (37 C.F.R. SECTION 1.8(a))

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the united States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to MAIL STOP PETITIONS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

4/11/05
Date

Nicole M. Aguirre
(type or print name of person mailing paper)

Nicole M. Aguirre
(signature of person mailing paper)

MAIL STOP PETITIONS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO RESET PERIOD FOR RESPONSE DUE TO POSTMARK DATE BEING LATER THAN MAIL DATE PRINTED ON PTO ACTION

Applicants respectfully request that the Supplemental Examiner's Answer mailed January 13, 2004, be re-mailed to the undersigned, thus resetting the reply.

1. This petition is being filed to restart the period of response to the PTO action indicated to have been mailed on January 13, 2004.

2. The response period was set for 2 months from the initial mailing date of the Supplemental Examiner's Answer – March 13, 2004.

3. Enclosed herewith is:

(a) evidence showing the date of receipt of the PTO action at the correspondence address;

(b) a copy of the envelope that contained the PTO action showing the mailed correspondence returned to the PTO by the Post Office due to an incorrect address – as well as the correct address of record at the time of mailing as indicated in the PTO "Bib Data Sheet".

It is respectfully requested that the Supplemental Examiner's Answer be re-mailed to the following current address associated with customer 50187:

Ronald I. Eisenstein
Nixon Peabody, LLP
100 Summer Street
Boston, Massachusetts 02110.

The Commissioner is authorized to charge any fees associated with this petition to the NIXON PEABODY LLP Deposit Account No. 50-0850. A duplicate copy of this paper is submitted herewith.

Date: 9/11/05

Respectfully submitted,

David S. Resnick (Reg. No. 34,235)
NIXON PEABODY LLP
100 Summer Street
Boston, MA 02110
(617) 345-6057

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Atty. Docket No. 700953-040736

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Dennis L. Panicali et al.		
Application No.:	07/579,269	Group No.:	1648
Filed:	09/05/1990	Examiner:	Laurie A. Scheiner
Title:	RECOMBINANT POX VIRUS FOR IMMUNIZATION AGAINST TUMOR-ASSOCIATED ANTIGENS		

CERTIFICATE OF MAILING (37 C.F.R. SECTION 1.8(a))

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Nicole M. Aguirre
(type or print name of person mailing paper)

Nicole M. Aguirre
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EVIDENCE AND STATEMENT ACCOMPANYING PETITION TO RESET PERIOD FOR RESPONSE DUE TO POSTMARK DATE BEING LATER THAN MAIL DATE PRINTED ON PTO ACTION

1. I, David S. Resnick, hereby state that the Action mailed by the PTO on January 13, 2004, as shown on the first page thereof which accompanies this petition, was received on February 4, 2005.

2. The evidence showing the date of receipt of the PTO action at the correspondence address of the applicant is as follows:

   (a) Copy of the Supplemental Examiner's Answer date stamped "Received February 4, 2005 NIXON PEABODY LLP".

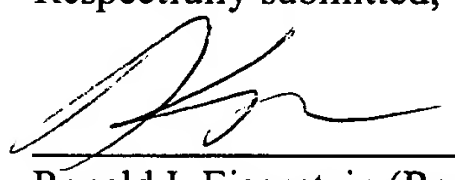
(b) Copy of the U.S. Post Office "Return to Sender" bar coded label dated January 21, 2004 and the original post marked envelope indicative of the Post Office return stamped received by TECH CENTER 1600/2900 on January 29, 2004;

(c) Copy of the Bib Data Sheet on file in the US PTO indicative of the correct address at the time of mailing.

I can state that the above evidence establishes the date of the postmark and the date of receipt of the Office Action because Applicants note that the Supplemental Examiner's Answer was mailed to Ronald I. Eisenstein at his previous firm, Dike, Bronstein, Roberts & Cushman. The Response was then returned to the U.S. Patent and Trademark Office and was not re-mailed until on or about February 2005. Applicants note that the Patent and Trademark Office had Mr. Eisenstein's correct mailing address as noted in the Bib Data Sheet attached to the Supplemental Examiner's Answer, a copy of which is enclosed herewith.

Date: 4/11/05

Respectfully submitted,



Ronald I. Eisenstein (Reg. No. 30,628)
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1663

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/579,269	09/05/1990	DENNIS L. PANICALI	ABT87-01	4396

7590 01/13/2004

RONALD I. EISENSTEIN
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EXAMINER	
SCHEINER, LAURIE A	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

40736

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 34

Application Number: 07/579,269
Filing Date: September 05, 1990
Appelants: PANICALI ET AL.

Ronald I. Eisenstein
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the Remand to the Examiner by the Board mailed August 7, 1998. In the remand, the Board expressed an intention to affirm the Office's rejections under one or more grounds as argued in the Examiner's Answer. However, the Board requested that the Office further consider the 35 U.S.C. § 112, first paragraph rejection in light of a prior art reference cited in the Final Rejection: the Lathe et al. reference. The Board has also requested that the Examiner reconsider the grounds of rejection in light of several previously unconsidered prior art references cited by the Board: the four Paoletti

et al. patents (Paoletti '112, '848, '330, '587), five references cited by Lathe, and the Schlom et al. abstract (Schlom). Upon consideration, the Office concludes, for the reasons set forth below, that the new references do not affect the analysis or rejections of the claims.

The Examiner has considered the four Paoletti patents and has determined that they are less relevant than, and do not add anything to the analysis of the claims over Lathe. The Examiner has also considered the five references cited by Lathe (Lathe references), and has found that they also add little to the determination of patentability of the application and claims at issue. The Lathe references provide little more than background in the art of the invention.

The Schlom reference is not quite so easily dismissed. At first glance, it appears relevant to the rejection based on §101 and §112 paragraph 1 of the United States Code. This reference will be addressed in more detail in the body of this Supplemental Answer, but upon consideration, the Office finds that the Schlom reference does not repair the deficiencies in the application's disclosure such that the claims may be allowed.

However, in light of the Applicants' failure to establish the utility and provide an enabling disclosure of the claimed invention, the Examiner feels that there is no current need to address the 35 U.S.C. § 103 rejections. Therefore, the §103 rejection to claims 15-22 as obvious over Lathe in view of Padhy et al., and further in view of Yamamoto et al. are hereby withdrawn.

1. Status of the Claims

The statement of the status of the claims contained in the Brief is correct. This appeal involves claims 15, 16, 18-22, 36, and 37.

2. Summary of the Invention

The summary of the invention contained in the Brief is correct.

3. Issues

The statement of the issues in the Brief is correct. This Supplemental Answer is intended as an addendum to the previous Examiner's Answer.

4. Grouping of the Claims

The Appellant's Brief states that the claims do not stand of fall together, but fails to provide any support for that statement as required under 37 C.F.R. 1.192(c)(7). The Appellant's statement that all claims are separately patentable is also unsupported.

5. Prior Art of Record

The following are lists of all priori art of record relied on by the Examiner in the Answer, as well as of those references considered by the Examiner for the purpose of responding to the Board's remand.

Prior Art Relied on by Examiner in the Answer

Allen et al., "Specificity of the T-cell Receptor: Two different Determinants are Generated by the Same Peptide and the I-A^k Molecule[1,2]," The Journal of Immunology, vol. 135, pp. 368-73 (1985).

Lathe et al. (Lathe), "Tumor Prevention and Rejection with Recombinant Vaccinia," Nature, vol. 326, pp. 878-80 (1987).

Padhy et al., " Identification of a Phosphoprotein Specifically Induced by the Transforming DNA of RAT Neuroblastomas," Cell, vol. 28, pp. 865-71 (1982).

Yamamoto et al., "Similarity of Protein Encoded by the Human c-erb-B-2 Gene to Epidermal Growth Factor Receptor," Nature, vol. 319, pp. 230-34 (1984).

Additional Prior Art Considered as per the Board's Request

Paoletti et al. (Paoletti '112), 4,603,112, July 29, 1986.

Paoletti et al. (Paoletti '848), 4,722,848, Feb. 2, 1988.

Paoletti et al. (Paoletti '330), 4,769,330, Sept. 6, 1988.

Paoletti et al. (Paoletti '587), 5,110,587, May 5, 1992.

The Lathe References

Drebin et al., "Monoclonal Antibodies Identify a Cell-Surface Antigen Associated with an Activated cellular Oncogene," Nature, vol. 312, pp. 545-48 (1984).

Koprowski et al., "Specific Antigen in Serum of Patients with colon Carcinoma," Science, vol. 212, pp. 53-56 (1981).

Peto, R. & H. Zur Hausen (Eds.), Banbury Report 21, Viral Etiology of Cervical Cancer, Cold Spring Harbor Laboratory, New York (1986).

Real, F.X. et al., "Class I (Unique) Tumor Antigens of Human Melanoma," Journal of Experimental Medicine, vol. 160, pp. 1219-33 (1984).

Ueda, R. et al., "Cell Surface Antigens of Human Renal Cancer Defined by Autologous Typing," Journal of Experimental Medicine, vol. 150, pp. 564-72 (1979).

6. Grounds of Rejection

This Supplemental Answer continues the analysis of the rejections based on 35 U.S.C. §101 and §112 paragraph 1.

7. Supplementary Response to the Argument

The claimed invention is a method of immunizing humans against human cellular oncogene encoded products by inoculating them with either a pox or vaccinia virus expressing the oncogene, proto-oncogene, or homologue thereto (all 3 inclusively

referred to as "oncogene"). The Appellants' claims have been rejected under 35 U.S.C. §101 for failure to establish the invention's utility, and under §112 paragraph 1 for failure to provide an enabling disclosure of the invention. Section 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

All of the claims at issue in this appeal are rejected under this section for failure to establish utility. As was argued in the Answer, this failure arises because the appellant's disclosure does not show that inoculating an individual with a virus expressing an oncogene (by expressing the oncogene product) would immunize that individual from tumors expressing such products.

In the Answer, the Examiner argued that the specification failed to show that such an inoculation would immunize an individual against tumors expressing oncogene products. The specification showed that while such an inoculation into mice seemed to cause them to reject tumors expressing the oncogene products, use of the same inoculation into rates failed to promote tumor rejection in rats. This showed that the mice could have been reacting because the oncogene was a foreign substance rather than because an immune response had been elicited. The failure of the rats to reject rat tumors expressing rat oncogene products created doubt that the claimed method would work in any situation where the subject was inoculated with a virus expressing a syngenic oncogene. This, in turn, created a question as to whether the claimed method would cause a human to reject tumors expressing human oncogene products. Thus, utility has not been shown.

Likewise, because the disclosure demonstrated that syngenic test subjects did not respond to the inoculation as the applicant claimed they should, the claims have not been enabled. Section 112 paragraph 1 of 35 U.S.C. reads as follows:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor for carrying out the invention."

The invention has not been enabled because the appellant did not show that the disclosed method of immunization would in fact immunize a human against a human oncogene product. Because the claimed method did not elicit an immune response in rate against rat oncogenes, the appellant has not shown that a human could be immunized against human oncogenes using the disclosed method. Since the method has not been shown to work, it is not enabled as required by §112 paragraph 1.

Effect of the Schlom Reference

The Schlom reference is an abstract of an article explaining the results of clinical trials of the disclosed method. The abstract states that the inoculation of a vaccinia virus expressing the human carcinoembryonic antigen (CEA) into cancer patients did yield an improved immune (CTL) response in those patients against cancer expressing CEA. However, while this may be encouraging, it is not sufficient to overcome the current rejections to the claims.

The claims on appeals all cover a virus expressing an oncogene, proto-oncogene, or an oncogene or proto-oncogene homologue product. See the Appendix to the Appeal Brief. Such genes have the potential to cause transformation of normal cells into tumor

cells if mutated from their wild-type form. Application, pp. 1, 3-4. Oncogenes may encode for proteins that operate inside the cell, or for cell surface proteins with internal effects (e.g. growth factor molecules). Application, pp. 3-4. The Applicant used an oncogene product in the viral antigen disclosed in the application pp. 24-36. It was this disclosed, oncogene product antigen that failed to work, thus giving rise to the rejections both for lack of utility and enablement.

Along with the oncogenes, Appellant's disclosure also mentioned another type of gene product that may be used in the immunization method disclosed. Application, p. 8. These tumor-associated molecules are not expressions of oncogenes, or even necessarily involved in cell transformation. Nevertheless, these molecules are still associated with tumors because they are expressed by tumor cells. Application, p. 8. The Appellants list CEA, the molecule tested in the clinical trials, as such a tumor-associated molecule, not as an oncogene product, pp.8.

Tumor-associated molecules are not expressions of oncogenes, and therefore do not fall within the invention claimed by the appellant. Genes encoding these molecules do not have the potential to transform cells, even where they may be involved in transformation, as do the oncogene antigens. The tumor-associated molecules are distinct from those molecules consisting if oncogene products. Similarly, the inoculation in the Schlom reference is distinct from the claimed invention. The effectivity of viral antigens using tumor-associated molecules does not establish to the patentability of the claimed method, which uses oncogene products as the antigen.

Nor can the successful use of such distinct molecules in a disclosed, but unclaimed, mode of use overcome a rejection based on an unsuccessful test of the

claimed method. Here, the claims are rejected because the Application failed to show the utility of, and to enable, the claimed mode of practicing the invention; i.e. using a viral antigen expressing an oncogene product. The Schlom reference does not relate to the claimed method. It shows only that a related, and disclosed, method may work. It is not sufficient to overcome the earlier evidence in the Application suggesting the inoperability of the claimed method itself. Thus, the Schlom reference does not establish utility of the invention, nor does it enable the disclosure. The reference is therefore not relevant in the present case.

Further Consideration of Lathe

Lathe discloses the use of recombinant vaccinia to elicit tumor immunity responses for tumors caused by the tumorigenic properties of the Polyoma virus. The authors of that reference took three tumor-specific antigens, three different early Polyoma proteins, and inserted each of the three into a different vaccinia recombinant. They found that two of the three recombinant vaccines lead to a regression of and, under certain circumstances, to an elimination of Polyoma transformed tumor cells injected into test animals. Their experiments showed that they could get such results in rats vaccinated both before and after inoculation with the tumor cells. While this reference does show potential promise for the future use of recombinant viral antigens in eliciting immune responses to tumors, it does not fill in the gaps of the Appellants' disclosure such that either the utility or enablement requirements are satisfied.

Lathe does not deal with syngenic oncogenes, as does the Appellants' invention, but with tumor-associated viral proteins. One of the elements of the Appellants' claimed invention is that the immune response be against a syngenic oncogene's product. The

Appellants' claims were rejected because they did not get such an immune response in response to inoculation with a viral antigen expressing that oncogene. Recognition of a foreign protein in an immune response is not a satisfactory substitute for recognition of a syngenic protein. Thus, Lathe is not relevant to the consideration of the claims under 35 U.S.C. § 101 and § 112 paragraph 1.

For the reasons stated above, it is believed that the rejections should be sustained.

This Application has been forwarded to the Board of patent Appeals and interferences for decision on the Appeal.

Respectfully submitted

James C. Housel
Supervisory Patent Examiner
Technology Center 1600

571-272-0902

Ronald I. Eisenstein
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Organization TC 1600 CMI Bldg./Room

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BIBDATASHEET

Bib Data Sheet

CONFIRMATION NO. 4396

SERIAL NUMBER	FILING OR 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/579,269	09/05/1990 RULE	424	1648	ABT87-01

APPLICANTS

DENNIS L. PANICALI, ACTON, MA;
RENE BERNARDS, BROOKLINE, MA;

**** CONTINUING DATA ***************************

This application is a CON of 07/092,036 09/02/1987 ABN

**** FOREIGN APPLICATIONS ********************

IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** SMALL ENTITY **
** 09/27/1990

Foreign Priority claimed ☐ yes ☐ no 35 USC 119 (a-d) conditions met ☐ yes ☐ no ☐ Met after Allowance Verified and Acknowledged Examiner's Signature Initials	STATE OR COUNTRY MA	SHEETS DRAWING 3	TOTAL CLAIMS 32	INDEPENDENT CLAIMS 9	

ADDRESS

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BOSTON ,MA 02110

TITLE

RECOMBINANT POX VIRUS FOR IMMUNIZATION AGAINST TUMOR-ASSOCIATED ANTIGENS

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